In The Specification:

Please replace the Sequence Listing (1 page) filed on April 19, 2002 with the substitute Sequence Listing (1 page) filed herewith.

Please replace the paragraph beginning at page 6, line 5, with the following rewritten paragraph:

As used herein, "analyte" refers to any atom and/or molecule; including their complexes and fragment ions. In the case of biological molecules/macromolecules or "biopolymers", such analytes include but are not limited to: proteins, peptides, DNA, RNA, carbohydrates, steroids, and lipids. Note that most important biomolecules under investigation for their involvement in the structure or regulation of life processes are quite large (typically several thousand times larger than H_2O) .

Please replace the paragraph beginning at page 19, line 2, with the following rewritten paragraph:

FIGURE 1 is a representation of derived data which characterizes a disease specific marker having a particular sequence (SEQ ID NO:1) useful in evidencing and categorizing at least one particular disease state[;]. The patients listed in the data table show the presence of the disease specific marker (SEQ ID NO:1) in their serum.

Please replace the paragraph beginning at page 19, line 6, with the following rewritten paragraph:

FIGURE 2 is the characteristic profile derived via SELDI/TOF MS of the disease specific marker of Figure 1. SEQ ID NO:1 is shown.

Please replace the paragraph beginning at page 22, line 19, with the following re-written paragraph:

Chelating [Sepharose] SEPHAROSE Mini Column

1. Dilute Sera in Sample/Running buffer;

2. Add Chelating [Sepharose] SEPHAROSE slurry to column and allow column to pack;

3. Add UF water to the column to aid in packing;

4. Add Charging Buffer once water is at the level of the resin surface;

5. Add UF water to wash through non bound metal ions once charge buffer washes through;

6. Add running buffer to equilibrate column for sample loading;

7. Add diluted serum sample;

8. Add running buffer to wash unbound protein;

9. Add elution buffer and collect elution fractions for analysis;

10. Acidify each elution fraction.

Please replace the paragraph beginning at page 36, line 2, with the following re-written paragraph:

The instant invention involves the use of a combination of preparatory steps in conjunction with mass spectroscopy and time-of-flight detection procedures to maximize the diversity of biopolymers which are verifiable within a particular sample. The cohort of biopolymers verified within such a sample is then viewed with reference to their ability to evidence at least one particular disease state; thereby enabling a diagnostician to gain the ability to characterize either the presence or absence of [said] at least one disease state relative to recognition of the presence and/or the absence of [said] <u>the</u> biopolymer.

In The Claims:

Claim 1. (currently amended) A biopolymer marker [having a sequence identified as SEQ ID NO:1 useful in indicating at least one particular disease state] peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 diagnostic for myocardial infarction.

Claims 2-35. (currently canceled).

Claim 36. (new) A method for diagnosing myocardial infarction comprising:

(a) obtaining a sample from a patient;

(b) conducting mass spectrometric analysis on said sample in a manner effective to maximize elucidation of discernible peptide fragments contained therein; and

(c) comparing mass spectrum profiles of a peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from said sample; wherein recognition of a mass spectrum profile in the sample displaying the characteristic profile of the mass spectrum profile for the peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 is diagnostic for myocardial infarction.

Claim 37. (new) The method of claim 36, wherein the sample is an unfractionated body fluid or a tissue sample.

Claim 38. (new) The method of claim 36, wherein said sample is selected from the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

Claim 39. (new) The method of claim 36, wherein said mass spectrometric analysis is Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS).

Claim 40. (new) The method of claim 36, wherein said patient is a human.

Claim 41. (new) A myocardial infarction diagnostic kit comprising: (a) a peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 and (b) an antibody that binds to said peptide in a sample from a patient.

Claim 42. (new) The diagnostic assay kit of claim 41, wherein said antibody is immobilized on a solid support.

Claim 43. (new) The diagnostic kit of claim 41, wherein said antibody is labeled.

REMARKS

Claim Status/Support For Amendments

No new matter has been added by the amendments to the specification.

Page 6 of the instant disclosure was amended to correct a typographical error.

The Brief Description of the Figures was amended to add sequence identifiers for the sequences disclosed in the figures and to correct typographical errors.

A protocol in the experimental section of the detailed description has been amended to properly identify the trademark SEPHAROSE using capitalization.

The abstract has been amended to remove the legal phraseology ("said").

Claim 1 has been amended. Claims 2-35 have been canceled. Claims 36-43 have been added. Claims 1 and 36-43 are pending in the instant application.

No new matter has been added by the addition of new claims 36-43. The subject matter of new claims 36-43 corresponds to the subject matter of canceled claims 3-28. The above additions to the claims also find basis in the original disclosure at page 12, lines 2-12; page 17, lines 7-14; page 18, lines 5-7 and page 27, lines 17-23. The method of claims 36-40 is described in detail at pages 20-27. Page 28,line 9 to page 29,line 5 refers to the use of

various types of samples and their measurement. Figure 1 shows data derived when using the claimed method on samples obtained from a human patient. Page 28, line 1 to page 33, line 2 describes kits and their contents contemplated for use with the claimed methods. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

Sequence Compliance

Applicants have reviewed the entire specification including the figures and the claims for sequence disclosures. The only sequence found to be disclosed is the amino acid sequence identified as SEQ ID NO:1. Applicants provided a Sequence Listing (in both paper and computer readable form) disclosing SEQ ID NO:1 on April 19, 2002. However, Applicants noted that the first amino acid residue of SEQ ID NO:1 (D, as disclosed by the sequence shown in the figures) was not included in the originally filed Sequence Listing. Applicants herein provide a diskette containing a substitute Sequence Listing in electronic computer readable form to replace the previously submitted copy (filed on April 19, 2002). The diskette submitted herewith contains a Sequence Listing which adds the first amino acid residue (shown in the figures) to SEQ ID NO:1. As shown in Figure 1, the marker identified in patient sera

consists of amino acid residues 2-14 of SEQ ID NO:1. When carrying out mass spectrometric procedures, it is possible to fragment a whole molecule, depending upon the enzyme used for digestion. A sequence is often predicted from these fragments but often the sequence is not identified completely. It is conventional in the art to show the missing portions of the predicted sequence in parentheses. The first (D) amino acid residue of SEQ ID NO:1 is a predicted residue as indicated by the parentheses in Figure 1. The peptide sequence without the predicted first amino acid residue was shown in the original specification at page 27, line 18 and is shown in the figures with the first predicted amino acid residue. Thus, no new matter is added, the substitute Sequence Listing is for the purpose of clarifying the use of parentheses only. Applicants also herein provide a substitute paper copy of the Sequence Listing as contained on the diskette filed herewith. The computer readable form of the substitute Sequence Listing is identical to the paper copy of the substitute Sequence Listing. The amendments to the claims and specification limiting the marker sequences to specific amino acid residues are also made for the purpose of clarification of the use of parentheses only. The claims as herein amended limit the marker sequence to amino acid residues 2-14 of SEQ ID NO:1.

Restriction/Election

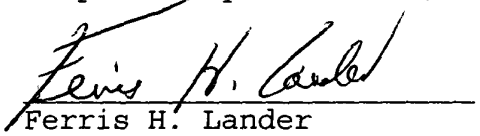
In a telephone conference on August 12, 2003, the Examiner indicated that a Restriction requirement would be necessary in the instant application. Applicants requested the entry of a Preliminary Amendment prior to the Restriction requirement. Applicants would elect the marker claim (claim 1) for examination on the merits when/if restriction is required. However, Applicants respectfully request that the Examiner consider re-joining the claims after the marker claim is found allowable.

The instant application is related in claim format to several pending applications of which serial number 09/846,352 is exemplary. The biopolymer marker of serial number 09/846,352 was found to be novel and subsequently claims reading on methods and kits limited to its use were rejoined with the claims reading on the biopolymer marker under *Ochai*. Similarly, if the peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 of the instant application is found to be novel, methods and kits limited to its use should also be novel. Thus, in an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner enter the new claims (36-43) added herein by amendment and consider rejoining them with claims reading on the biopolymer marker consisting of amino acid residues 2-14 of SEQ ID NO:1 when such claims to the biopolymer marker are found allowable.

CONCLUSION

Applicants now respectfully request an examination on the merits in the above-referenced application.

Respectfully submitted,



Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)

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